Featured Clinical Research

Comparison of Safety and Efficacy of CYPHER® Stent and ENDEAVOR® Stent in Patients with Acute ST Elevation Myocardial Infarction(STEMI) undergoing emergency PCI and Analysis of Current Status of Emergency PCI Green Channel in China

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Background: To compare the Safety and Efficacy of CYPHER® Sirolimus Stent and ENDEAVOR® Zotarolimus Stent in Patients with Acute STEMI undergoing emergency PCI, and to analysis Current Status of Emergency PCI Green Channel for Patiens with STEMI in China.

Methods: 1020 patients were to be randomized, these patients were STEMI within 12 hours preparing emergency PCI, with "De novo"lesions in native coronary arteries, and informed consent were written. and 145 cases were exclused(14.2%), totally 875 patients entered the study, 449 patients in ENDEAVOR group and 426 patients in CYPHER group, totally 761 patients (86.9%) with 6-months Clinical follow-up. The primary endpoints were cardiac mortality, myocardial infarction, and target lesion revascularization (TLR) at 6 months.

Results: The Baseline Clinical Characteristics and Lesion Characteristics between 2 groups were no significant, Myocardial Infarction at 6 months between 2 groups were 2and 3(P =0.61),Stent Thrombosis at 6 months between 2 groups were both 2 cases(P =0.96),Stent restenosis at 6 months between 2 groups were 5 and 1(P=0.09),Target Lesion Revascularization at 6 months at 6 months between 2 groups were 6 and 3(P =0.35),Cardiac death at 6 months were 12 and 9(P =0.56),Composite MACE at 6 months at 6 months were 20(4.5%)and 15(3.5%),P =0.48. The analysing of Emergency Green Channel showed that the mean time of door to ballon was 119.2±80.1 minutes (40~710 min), and only 47.6% patients whose D T B time was less than 90 minutes.

Conclusion: 1. There was no signal differential profile between Cypher and Endeavor during 6 months in safety and efficacy. The antirestenotic efficacy of Endeavor was somewhat inferior to the Cypher stent in Patients with STEMI undergoing emergency PCI at 6-month follow-up. 2.Currently, AMI patients of Chinese first class hospital are treated delayed seriously. There is still a big gap with PCI Guide which require 90min from door to balloon.

Baseline Clinical Characteristics

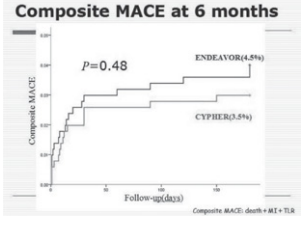
	END	CYP	P
Age(yrs)	59.6	60.2	NS
Women(%)	18.4	18.2	NS
Diabetes(%)	16.7	19.4	NS
Hypertension(%)	48.0	51.6	NS
Current smoker (%)	58.8	55.1	NS
Hypercholesterolemia (%)	18.2	17.3	NS
Previous MI(%)	2.5	2.0	NS
Anterior MI(%)	48.8	50.9	NS
EF(%)	56.3±9.9	54.4±9.3	NS

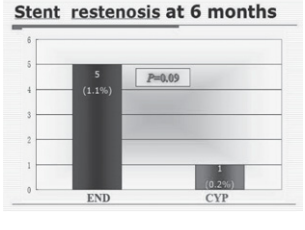
Lesion Characteristics

	END	CYP	P
LAD(%)	49.0	44.5	NS
LCX(%)	14.2	17.5	NS
RCA(%)	36.8	38	NS
TIMI 0(%)	65.4	60.4	0.08
Heavy thrombus(%)	63.6	64.1	NS
Lesion type A (%)	10.8	11.5	NS
Lesion type B (%)	50.9	55.6	NS
Lesion type C (%)	38.3	32.9	NS

PCI Information

	END	CYP	P
Radial(%)	53.1	52.4	NS
IABP(%)	5.9	6.3	NS
2b/3a(%)	51.8	53.9	NS
Stents (n)	1.44±0.6	1.35±0.6	0.03
Stent length (mm)	24.1±5.6	24.7±6.2	0.03
Stent diameter (mm)	3.1±0.4	3.1±1.1	NS
Eelective PCI(%)	12.4	14.9	NS





Long-term Clinical Results from the All-comers LEADERS Trial: 4 Year Follow-up Data.

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Background: There is concern of an increased incidence of very late stent thrombosis, associated with early generation DES potentially related to the durable polymer. The Biolimus A9™ eluting stent platform (BES) releases biolimus from an abluminal biodegradable polymer, polylactic acid (PLA), which is fully absorbed after 6-9 months. The LEADERS trial aimed to compare the safety and efficacy of BES with an established stent platform releasing sirolimus from a durable polymer (SES) in a large scale, all-comers, non-inferiority trial. The purpose of this presentation is to present the 4- year follow-up data to determine whether there are differences between the biodegradable BES platform as compared to the durable polymer SES platform.

Methods: LEADERS is a multi-center, randomized, assessor-blind, non-inferiority trial performed at 10 European sites in an all-comers, "real world" patient population without limitation with respect to lesion length, number of treated lesions or vessels as well as clinical indication (chronic stable angina vs. acute coronary syndromes). A total of 1,707 patients were enrolled and randomly allocated 1:1 to BES or SES. The primary endpoint was MACE (a composite of cardiac death, MI, or clinically-indicated TVR) at 9 months. Secondary endpoints include death, cardiac death, MI, ST (ARC defined), TLR and TVR. All patients are followed up to 5 years.

Results: BES sustained its non-inferiority to SES in terms of the primary endpoint of MACE up to 4 year follow-up with a trend towards improved outcomes at 4 years (18.7% for BES vs. 22.6% for SES, RR (95% CI): 0.81 (0.66 to 1.00), p non-inf<0.0001,psup=0.051). Very late definite stent thrombosis (0.4% for BES vs. 1.8% for SES, RR(95% CI): 0.20 (0.06 to 0.67), psup=0.004) as well as very late definite/ probable stent thrombosis (0.7% for BES vs. 2.4% for SES, RR (95% CI): 0.29 (0.12 to 0.73), psup=0.005) were less frequent with BES than SES at 4 years. The 4 year outcomes are summarized in table 1.

Conclusion: Our results suggest that BES represents a safe and effective alternative to SES with robust clinical results up to 4-year follow-up.

Table 1. LEADERS 4-year outcomes

Outcome	BES (N=857)	SES (N=850)	Risk Ratio (95% CI)	p value[1]
MACE[2]	160 (18.7%)	192 (22.6%)	0.81 (0.66 to 1.00)	**0.051**
Cardiac Death	51 (6.0%)	57 (6.7%)	0.88 (0.60 to 1.29)	0.514
MI	71 (8.3%)	73 (8.6%)	0.96 (0.69 to 1.33)	0.803
clinically-indicated TVR	91 (10.6%)	110 (12.9%)	0.80 (0.61 to 1.06)	0.122
Definite ST	20 (2.3%)	32 (3.8%)	0.62 (0.35 to 1.08)	0.086
Very Late Definite ST	3 (0.4%)	15 (1.8%)	0.20 (0.06 to 0.67)	**0.004**
Definite/Probable ST	29 (3.4%)	39 (4.6%)	0.73 (0.45 to 1.19)	0.204
Very Late Definite/Probable ST	6 (0.7%)	20 (2.4%)	0.29 (0.12 to 0.73)	**0.005**

1. p values for superiority
2. MACE: a composite endpoint of cardiac death, MI and clinically-indicated TVR

Two-year results from a Randomized Comparison of Everolimus-Eluting and Sirolimus-Eluting Stents in Patients Treated with Percutaneous Coronary Intervention (SORT OUT IV Trial)

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Background: The sirolimus-eluting stent has demonstrated the least amount of late lumen loss among previously released drug-eluting stents, but its long-term safety and efficacy have not been compared head-to-head with the next-generation everolimus-eluting stent

Methods: The Scandinavian Organization for Randomized Trials with Clinical Outcome (SORT OUT) IV was a randomized multicenter, open-label, all-comer, two-arm, non-inferiority trial comparing the everolimus-eluting stent with the sirolimus-eluting stent in patients with coronary artery disease. The primary end point was a composite of safety (cardiac death, myocardial infarction, definite stent thrombosis) and efficacy (target vessel revascularization) parameters. Intention-to-treat analyses were done at 9-month (primary end point) and two-year follow-up.

Results: 1,390 patients were assigned to receive the everolimus-eluting stent, and 1,384 patients were assigned to receive the sirolimus-eluting stent. At 9-month follow-up, 68 [4.9%] patients treated with the everolimus-eluting stent versus 72 [5.2%] patients treated with the sirolimus-eluting stent experienced the primary end point (hazard ratio (HR) = 0.94; 95% confidence interval (CI): 0.67 to 1.31) (p for non-inferiority = 0.01). Two-year results will be available at the presentation.

Conclusion: Two-year results will be available at the presentation.

Clinical Evaluation of the IN.PACT Drug-eluting Balloon for Treatment of Femoro-popliteal Arterial Disease: Twelve Month Results from a Multicenter Italian Registry

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Background: This study evaluated the use of a drug-eluting balloon (DEB) for treatment of femoropoliteal arterial disease.Conventional balloon angioplasty and stenting in this setting is associated with a high restenosis rates within
12 months post-procedure. Recent data suggest that use of DEBs may reduce restenosis. Twelve month outcomes following DEB use with provisional stenting are described.

Methods: This prospective registry enrolled patients (Rutherford class 2, 3, or 4) with reference vessel diameter of 3 to
7 mm and lesion/occlusion length ≤15 cm. Endpoints included primary patency rate, target lesion revascularization (TLR), and changes in Rutherford class and ankle-brachial index (ABI). Walking capacity, absolute claudication distance (ACD), and quality of life (QOL) were also assessed

Results: At 12 months follow-up, 92/105 patients (87.6%) were evaluable. Baseline ABI was 0.56 ± 0.15. Baseline Rutherford classification was 26.7% for class 2 and 64.8% for class 3. Most lesions were located in the superficial femoral artery (77.1%).